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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,832	07/16/2007	Changlu Liu	PRD2203USPCT	8383

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,832	LIU ET AL.	
	Examiner	Art Unit	
	ABDEL A. MOHAMED	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF PRIORITY, STATUS OF THE APPLICATION AND CLAIMS

1. This application is filed under 35 U.S.C. 371 on 07/16/07 having a filing date of 03/29/05 of PCT/US05/10279. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. Claims 1-10 are present for examination.

OBJECTION TO THE SPECIFICATION

2. The continuity data of this application should be updated in the specification.

CLAIMS REJECTION-35 U.S.C. 112, 1st PARAGRAPHS

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The claims should be specific and have a structural utility which can be useful, for example in constructing the PK2β peptide in the methods of treatment of diseases or disorders of the invention because independent claims 1-3 are directed to an isolated and purified peptide consisting essentially of an amino acid

sequences selected from the groups consisting of SEQ ID NO:1 and SEQ ID NO:2 or to an isolated and purified PK2β peptide having an amino acid sequence corresponding to SEQ ID NO:1 and SEQ ID NO:2, but not by any of the methods of treatment of diseases or disorders disclosed in the instant specification or claimed in the instant invention of claims 4-10 is/are critical or essential to practice the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The instantly claimed invention as claimed in claims 1-3 is directed to an isolated and purified peptide consisting essentially of an amino acid sequences selected from the groups consisting of SEQ ID NO:1 and SEQ ID NO:2 or to an isolated and purified PK2β peptide having an amino acid sequence corresponding to SEQ ID NO:1 and SEQ ID NO:2, however, the claims do not recite the essential utility for methods of treating diseases or disorders by administering the claimed peptides as disclosed in the instant specification and claimed in claims 4-10. Thus, the claims lack clarity as having specific and functional utility because no method of treatment has been indicated in the claims, particularly in independent claims 1-3 and is not clear as to the contribution of the isolated and purified peptides as claimed.

4. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description in the instant

specification for the claimed method for **treating a patient diagnosed with a disease or disorder mediated by PK1 activity,** comprising administering to a subject in need of treatment thereof an effective amount of a pharmaceutically active amount of a composition according to claim 4 as claimed in claims 7-10. The instant specification on pages 7-15 demonstrates the isolation, preparation, purification and biochemical characterization of prokineticin 2β peptide (PK2β). Also, on page 6, paragraph 2 to page 7, lines 1-4 and on page 18-19, the instant specification discloses the protocols by incorporating various references of how to prepare the pharmaceutical formulations of PK2β peptides with exemplary dosage levels from 0.001 to 1000 μg/kg/subject, more preferably 0.001 to 100 μg/kg intended to be administered to treat the various lung diseases or disorders as well as the numerous gastrointestinal diseases or disorders in the manner claimed in the instant invention of claims 4-10 by employing the PK2β peptides claimed in claims 1-3.

However, there is no **even one example** for the pharmaceutical formulation administered to a subject in need of treatment thereof an effective amount of a composition according to claim 4 comprising by administering the pharmaceutical formulation of SEQ ID NO:1 or SEQ ID NO:2 of claims 1-3 for the various disease or disorders claimed in claims 7-10. There is no *in vivo* showing for the effectiveness of the method for **treating a patient diagnosed with a disease or disorder mediated by PK1 activity**, comprising administering to a subject in need of treatment thereof an effective amount of a composition according to claims 1-3 in the manner claimed in claims 4-10.

CLAIM REJECTION-35 U.S.C. § 102(b)

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Ames, Jr. et al (US 2003/0059856 A1). The prior art of Ames, Jr. et al is directed like the instantly claimed invention of claims 1, 2, 4, 5 and 7-10 to claimed isolated and purified peptide consisting essentially of an amino acid sequence of SEQ ID NO:1 administered to a patient diagnosed with a disease or disorder mediated by PK1 activity, wherein the disease or disorder is a lung disease or disorder such as asthma or parasitic diseases and wherein the disease or disorder is a gastrointestinal disease or disorder such as diabetes. The sequence disclosed in the prior art t SEQ ID NO:14 (i.e., residues 28-83) is identical with claimed SEQ ID NO:1 (i.e., residue 1-56). The prior art SEQ ID NO:14 and the claimed SEQ ID NO:1 is used for the same purposes of treating diseases or disorders such as asthma and diabetics (See e.g.,

abstract and paragraphs 0183-0185) as directed to claims 1, 2, 4, 5 and 7-10. Thus, in the absence of evidence to the contrary or specific structural limitations, the prior art discloses the invention substantially as claimed, and as such anticipates claims 1, 2, 4, 5 and 7-10 as drafted.

6. Claims 1, 2, 4, 5, 9 and 10 are rejected under 102(e) as being anticipated by Ferrara et al (US 2003/0092623 A1). The prior art of Ferrara et al is directed like the instantly claimed invention of claims 1, 2, 4, 5, 9 and 10 to claimed isolated and purified peptide consisting essentially of an amino acid sequence of SEQ ID NO:1 administered to a patient diagnosed with a disease or disorder mediated by PK1 activity, wherein the disease or disorder is a gastrointestinal disease or disorder such as diabetes. The sequence disclosed in the prior art t SEQ ID NO:2 (i.e., residues 28-83) is identical with claimed SEQ ID NO:1 (i.e., residue 1-56). The prior art SEQ ID NO:2 and the claimed SEQ ID NO:1 is used for the same purposes of treating diseases or disorders such as diabetes (See e.g., paragraphs 0086, 0094, 0095, 0309-0311, 0314, 0315, 0329, 0337 and 0339) as directed to claims 1, 2, 4, 5, 9 and 10. Thus, in the absence of evidence to the contrary or specific structural limitations, the prior art discloses the invention substantially as claimed, and as such anticipates claims 1, 2, 4, 5, 9 and 10 as drafted.

7. Claims 1, 3, 4 and 6 are rejected under 102(e) as being anticipated by Zhou et al (US 2003/0235535 A1). The prior art of Zhou et al is directed like the instantly claimed invention of claims 1, 3, 4 and 6 to claimed isolated and purified peptide consisting

essentially of an amino acid sequence of SEQ ID NO:2 administered to a patient diagnosed with a disease or disorder mediated by PK1 activity in general. The sequence disclosed in the prior art t SEQ ID NO:8 (i.e., residues 1-56) is identical with claimed SEQ ID NO:2 (i.e., residue 1-56). The prior art SEQ ID NO:8 and the claimed SEQ ID NO:2 are used for the same purposes of treating diseases or disorders in general (See e.g., paragraphs 0141 and 0142) as directed to claims 1, 3, 4 and 6. Thus, in the absence of evidence to the contrary or specific structural limitations, the prior art discloses the invention substantially as claimed, and as such anticipates claims 1, 3, 4 and 6 as drafted.

CONCLUSION AND FUTURE CORRESPONDANCE

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABDEL A. MOHAMED whose telephone number is (571)272-0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mohamed/A. A. M./
Examiner, Art Unit 1654

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654